

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC-9267		FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/JP2004/011013		International filing date (day/month/year) 27.07.2004		Priority date (day/month/year) 30.07.2003
International Patent Classification (IPC) or national classification and IPC C07D215/38, A61K31/4704, A61P11/00, A61P43/00				
Applicant DAINIPPON INK AND CHEMICALS, INC.				

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 14, 15

because:

☒ the said international application, or the said claims Nos. 14, 15

relate to the following subject matter which does not require an international preliminary examination (*specify*):

The invention set forth in claims 14 and 15
relates to a method of treatment of the human body by
therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 14, 15

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement	
Novelty (N)	Claims <u>1-13, 16</u> YES Claims _____ NO
Inventive step (IS)	Claims <u>1-13, 16</u> YES Claims _____ NO
Industrial applicability (IA)	Claims <u>1-13, 16</u> YES Claims _____ NO
2. Citations and explanations (Rule 70.7)	
	Document 1: JP 9-255659 A
	Document 2: Aoki, Y. et al., "Inhibitory effect of a novel quinolinone derivative, TA-270, on asthmatic inflammatory responses in sensitized guinea pigs", European Journal of Pharmacology, 2000, Vol. 409, No. 3, pages 325 to 330
	Document 3: John E. Repine et al., "Oxidative Stress in Chronic Obstructive Pulmonary Disease", American Journal of Respiratory and Critical Care Medicine, 1997, Vol. 156, pages 341 to 357
	Document 4: Yasuyuki Yoshizawa, Megumi Sawada, "Steroid-yaku no Tsukaikata", Medicina, 1993, Vol. 30, No. 12, pages 2148 and 2149
	Reference document 2 submitted by the applicant: Walda IC., "Diet and 20-year chronic obstructive pulmonary disease mortality in middle-aged men from three European countries", European Journal of Clinical Nutrition, 2002, Vol. 56, pages 638 to 643
	Reference document 3 submitted by the applicant: Takahide Izumi, "Mansei Heisoku Seibai Shikkan Q&A",

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

Revised Edition, Iyaku Jaanarusha, 2000, pages 85 to 87

[1] The inventions set forth in claims 1 to 13 and 16 are not disclosed in any of the documents cited in the international search report, and are therefore novel and involve an inventive step.

Document 1 indicates that a 7-amino-quinolinone derivative is used as an anti-allergy agent, and document 2 indicates that a 7-amino-quinolinone derivative has an antioxidant activity which removes active oxygen, and that it reduces inflammatory cells such as acidophilic leukocytes and neutrophilic leukocytes in the lungs.

Meanwhile, document 3 indicates that antioxidants are used in the treatment of COPD, and that steroid agents used in the treatment of allergic dermatitis are used in the treatment of COPD.

However, as indicated in reference document 2 submitted by the applicant in the response to the written opinion dated 24 February 2005, all antioxidants are not necessarily effective in the treatment of COPD, and as indicated in reference document 3 submitted in the above response to the written opinion, anti-allergy agents should be distinguished from steroid agents, therefore the inventions set forth in claims 1 to 13 and 16 involve an inventive step.